Petition

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IN THE

Supreme Court of the United States

OCTOBER TERM 1981

NDM CORPORATION,
Petitioner,

v.

HAYES PRODUCTS, INC., and
JOSEPH H. JOHNSON,
Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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QUESTIONS PRESENTED

1. Are there two separate tests of obviousness, the first under 35 U.S.C. § 103 and the second a more strict synergistic test applied only to combination patents?

2. Did the Ninth Circuit err by failing to consider the district court's finding that the patented invention produced "unexpected" results in connection with its application of the test of 35 U.S.C. § 103 because it considered such a finding relevant only to a separate synergistic test?*

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*Colgate-Palmolive Corporation is the parent Corporation of NDM Corporation. Paragon Development Company is the owner of Hayes Products, Inc. Joseph N. Johnson has no present ownership interest in Paragon Development Company or Hayes Products, Inc.

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PETITION FOR WRIT OF CERTIORARI TO
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Petitioner, NDM Corporation, prays that a Writ of Certiorari issue to review the judgment of the United States Court of Appeals for the Ninth Circuit.

OPINIONS BELOW

The opinion of the court of appeals is reported at 641 F.2d 1274 and is reprinted

as Appendix A to this Petition. The Findings of Fact and Conclusions of Law made by the District Court for the Western District of Washington, which are unreported, are reprinted as Appendix B.

JURISDICTION

The judgment of the court of appeals was filed on March 16, 1981. On June 5, 1981, petitioner's Petition For Rehearing was denied and the suggestion for a rehearing en banc was rejected. By Order filed July 8, 1981, the court of appeals stayed the entry of its mandate till July 24, 1981, to allow the filing of this Petition for Certiorari. The jurisdiction of this court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

35 U.S.C. § 103. Conditions for patentability; non-obvious subject matter.

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in Section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

STATEMENT OF THE CASE

A. The Issue

Petitioner, NDM Corporation, seeks review of the decision of the Court of Appeals for the Ninth Circuit affirming the judgment of the district court which held petitioner's medical electrode patent invalid as a result of the misapplication of 35 U.S.C. § 103. Jurisdiction in the district court was proper under Title 28, §§ 1338(a) and 1400(b).

The court of appeals postulated two separate tests of patentability, the

first being the test of § 103 and the second being a more strict "synergistic" test which was to be applied only to combination devices, and only after a patent passed the first test.[1]

The district court found that the invention of U.S. Patent No. 3,701,346 produced "unexpected, substantial improvements in offset voltage . . ."[2] The court of appeals should have, but did not, consider this finding in connection with its application of 35 U.S.C. § 103 under the principles set forth in Graham v. John Deere Co.[3] Such a finding was of critical relevance to the evaluation of the differences between the prior art and the claimed invention. The court of

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[1] A-26 to A-28.

[2] A-29 at n.20; B-45, B-46, F.F. 71.

[3] 383 U.S. 1, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966).

appeals did not consider this finding under its § 103 test because it assumed that it applied only to a separate "synergistic" test. Further, since it found the invention obvious under § 103 it never applied this latter test because it concluded that a lack of synergism was subsumed within its finding of obviousness.[4] Thus, the district court's finding that the invention of the '346 patent produced "unexpected" improvements over the prior art was never considered by the court of appeals.

B. The Opinions Below

The district court made seventy-nine findings of fact to support its determination that the key claims of all four of plaintiff's medical electrode patents were invalid. Only that portion of the decision relating to U.S. Patent No. 3,701,346

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[4] A-27.

covering the first practical, long term, ready-to-use, disposable heart monitoring electrode was appealed by petitioner. The district court, in finding the '346 patent to be invalid, made no reference to the statutory presumption of patent validity;[5] took judicial notice of the obviousness of the patentable differences between the prior art and the '346 patent;[6] and merely substituted its judgment for that of the Patent Office by holding the patent invalid over the same Baum et al.[7] reference which was considered and rejected by the Patent Office prior to issuance of the patent.

The court of appeals found: the district court's failure to make an express finding that the statutory presumption of

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[5] 35 U.S.C. § 282.

[6] B-41, B-42; F.F. 63.

[7] Baum et al., U.S. Patent No. 3,187,745.

validity had been overcome was not prejudicial error;[8] the district court's use of "judicial notice" to be improper but mere harmless error;[9] and, affirmed the district court's holding of invalidity, again principally relying upon the same Baum et al. reference which had been considered and rejected by the Patent Office.[10]

ARGUMENT

This Court should review the present case to eliminate the conflict among the circuits on the issue of whether synergism is a separate test of patentability and to correct the Ninth Circuit's erroneous application of the obviousness test of 35 U.S.C. § 103.

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[8] A-14.

[9] A-22 at n.18.

[10] A-23 to A-25.

1. The Conflict Among the Circuits

In its opinion in this case, the Ninth Circuit not only postulated synergism as a separate test of patentability, but also specifically made reference to the fact that both the Seventh and Tenth Circuits had "recently rejected synergism as a separate test of patentability because of its inconsistency with § 103 analysis".[11]

Petitioner submits that the Ninth Circuit's specific reference to the conflicting decisions of other circuits is tantamount to a direct request to this Court to clarify what has become a near impossible situation for patent owners, the public, and the courts themselves. As shown by the decision in this case, the

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[11] A-27; cf. Republic Industries, Inc. v. Schlage Lock Co., 592 F.2d 963 (7th Cir. 1979); Plastic Container Corp. v. Continental Plastics, 607 F.2d 885 (10th Cir. 1979), cert. denied, 444 U.S. 1018, 100 S. Ct. 672, 62 L. Ed. 2d 648 (1980).

test of patent validity under 35 U.S.C. § 103 in the Ninth Circuit is unquestionably different from the test applied in the Seventh and Tenth Circuits.

Patent validity should not turn upon the local in which a patent is legally tested. The Seventh Circuit's decision in Republic Industries, Inc. v. Schlage Lock Co.[12] presents a well-reasoned, detailed rejection of synergism as a separate test of patent validity, the court concluding that it will continue to apply the Graham analysis as the exclusive means by which to measure non-obviousness under § 103. The Republic Industries decision cannot be reconciled with the Ninth Circuit's view expressed in its Opinion in this case that for combination patents there is a separate synergistic test which "is a much more stringent rule

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[12] Supra at n. 11.

of patentability than the usual Section 103 test. . . ."[13]

The Seventh, Ninth, and Tenth Circuits have clearly expressed their respective and divergent views as to the proper test of obviousness. The Ninth Circuit has gone further and acknowledged and made reference to the conflict between its view and that of those other circuit courts. This petition squarely places the resolution of this conflict in the hands of this Court.

2. The Error of the Ninth Circuit

Petitioner's claim is that the Ninth Circuit, by erroneously emphasizing synergism as a separate test of patentability, has misapplied the proper test under 35 U.S.C. § 103 as outlined by this Court in Graham v. John Deere Co.[14] The result

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[13] A-27, A-28.

[14] 383 U.S. 1, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966).

in the present case is that an invention which the Ninth Circuit acknowledged produced " . . . surprising and unexpected improvements in offset voltage readings",[15] has been found obvious and the patent covering the invention held invalid. The district court found that these improvements were "unexpected" by the inventors who were men skilled in the relevant art.[16] Such a finding should have been considered by the court in connection with its application of the three-part factual test of Graham v. John Deere Co. Instead, in finding the '346 patent to be obvious over the Baum et al. '745 prior patent, the Ninth Circuit stated:

> It may well be as NDM argues that the '346 was an improvement over the '745, achieving a more stable gel column when applied to the skin.

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[15] A-29 n. 20.

[16] B-45, B-46, F.F. 71.

> But "[i]n applying Section 103 . . . the test is not whether the object is an improvement in the art; . . ." but whether an improvement is obvious to one skilled in the art.[17]

The Ninth Circuit should have answered this last question by reference to the district court's finding that the improvement was unexpected, and thus not obvious, to a man skilled in the art, and then found the invention of the '346 patent to be non-obvious. The Ninth Circuit failed to reach this seemingly apparent conclusion because of its erroneous view that the district court's finding related only to the separate test of synergism, which test the court never reached.

The Ninth Circuit early adopted a test of obviousness for combination patents which was more strict than the test for

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[17] A-24, A-25.

non-combination devices. This more strict test was that the combination must produce "unusual or surprising" results.[18] This special standard for combination patents, however, was to be incorporated in and considered in connection with the standard of Graham v. John Deere Co.

If the Ninth Circuit were still properly applying this test which was first postulated by this Court in A. & P. Tea Co. v. Supermarket Corp.,[19] and followed in United States v. Adams, [20] petitioner's '346 patent would have been held valid in view of the district court's unchallenged factual finding that the invention of this patent possessed precisely such attributes.

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[18] Regimbal v. Scymansky, 444 F.2d 333 (9th Cir. 1971).

[19] 340 U.S. 147 at 152, 71 S. Ct. 121, 95 L. Ed. 2d 162 (1950).

[20] 383 U.S. 39, 86 S. Ct. 708, 15 L. Ed. 2d 572 (1966).

The Ninth Circuit's use of a separate synergism test erroneously prevents that court from considering findings and evidence relevant to the key issue in the Graham v. John Deere Co. analysis, namely, the evaluation of the differences between the invention and the prior art in light of the level of skill of a man skilled in the art.

This Court must speak to eliminate synergism as a separate test of patent validity or the Ninth Circuit will continue to improperly apply the obviousness standard of 35 U.S.C. § 103.

Respectfully submitted,

GRAYBEAL & UHLIR

By: JAMES R. UHLIR
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APPENDIX A

NDM CORPORATION, Appellant,

v.

HAYES PRODUCTS, INC.,
and Joseph H. Johnson, Appellees.

No. 77-3900.

United States Court of Appeals,
Ninth Circuit

Argued and Submitted April 10, 1980

Decided March 16, 1981

Patentee brought action alleging infringement of medical electrode patents. The United States District Court for the Western District of Washington, Donald S. Voorhees, J., entered judgment for defendants, and plaintiff appealed. The Court of Appeals, Goodwin, Circuit Judge, held that District Court's findings supporting its conclusion that plaintiff's patents were invalid for obviousness were not clearly erroneous.

Affirmed.

1. Patents 112.1

Presumption of validity of a patent issued by the U.S. Patent Office dissipates by a showing that pertinent prior art was not cited to the patent examiners; prior art is pertinent if it discloses something not disclosed by other prior art. 35 U.S.C.A. § 282.

2. Patents 324.56

In patent infringement case, district court's failure to make an express finding that statutory presumption of validity had been overcome was not prejudicial error. 35 U.S.C.A. § 282.

3. Patents 112.6

In patent infringement case, presumption of validity of medical electrode patents was overcome by prior pertinent art not before the patent examiners. 35 U.S.C.A. §§ 103, 282.

4. Patents 18

In determining obviousness of a patent, trial court must: determine scope and content of prior art; ascertain differences between prior art and the claimed invention, and measure their differences by level of ordinary skill possessed by a person familiar with the pertinent art; relevant subconsiderations include commercial success of the invention, extent to which it resolved long-felt needs, and difficulty of the problem solved by the invention. 35 U.S.C.A. § 103.

5. Patents 328(2)

In infringement case, district court's factual findings supporting conclusion of obviousness of claims 15 and 17 of medical electrode patent No. 3,701,346 and claims one and eight of medical electreode patent No. 3,820,531 were not clearly erroneous.

6. Patents 312(2), 324.56

In infringement action regarding patented medical electrode, trial court correctly admitted as prior art publications in which another patented electrode was described, and thus the allegedly improper admission of the described electrode itself as part of prior art did not prejudice patentee.

7. Patents 36.2(1)

Commercial success of a patented product and its resolution of long-standing problems in its field are relevant to determine patentability.

8. Patents 26(2)

Patents may be issued for inventions which combine elements existing in prior art if the result is unusual or surprising.

9. Patents 314(6)

In infringement action, trial court's conclusion that medical electrode patents

were invalid for obviousness subsumes within it a finding that the patents lacked synergism.

Appeal from the United States District Court for the Western District of Washington.

Before SKELTON,* GOODWIN and FERGUSON, Circuit Judges.

GOODWIN, Circuit Judge.

NDM Corporation appeals from a judgment in a patent infringement action that various claims of medical electrode patents which had been assigned to NDM were invalid for obviousness. We affirm.

NDM began,[1] in 1969, to develop medical electrodes for use in the electrocardiographic monitoring of heart patients.

*The Honorable Byron G. Skelton, Senior Judge, United States Court of Claims, sitting by designation.

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[1] Bionetics, Inc. was NDM's predecessor corporation. Bionetics developed the '807 and '346 patents. In March 1972,

Initially, NDM attempted to manufacture a "dry" electrode that would be activated by moisture in the patient's skin, rather than by application of a "wet" electrode gel. These efforts proved unsuccessful and NDM subsequently decided to develop an improved "wet" electrode.

The first product of these efforts was U.S. Patent No. 3,696,807 ("the '807 patent"), filed on February 13, 1970, issued on October 10, 1972. In laymen's terms, the '807 medical electrode patent was a rigid, nonconductive electrode gel cup which had a snap fastener mounted in its base. An elastic sheet covered the cup. This elastic, when pressed against a

(Footnote 1 continued)

Bionetics and the original NDM corporation, which marketed Bionetics electrodes, merged. The surviving corporation, appellant NDM Corporation, acquired title to the Bionetic medical electrode patents. Hereafter, "NDM" refers to its predecessor corporation where appropriate.

patient's skin, would adhere, forming a seal. Because of this seal, electrolyte gel remained in the cup, rather than leaking and causing the electrode to become loose. The snap fastener provided conduction. Increased adhesion facilitated long-term cardiac monitoring. The '807 design was not "pre-gelled." Electrolyte gel had to be added to the electrode cup at the time it was applied to the patient.

NDM's next development was a "pre-gelled," "ready-to-use" electrode, U.S. Patent No. 3,701,346 ("The '346 patent"), filed on January 4, 1971. In addition to the elements of the '807 patent, the '346 patent had an absorbent pad prefilled with electrolyte gel. The attached pad, which remained out of the electrode cup during storage, compressed into the cup when the electrode was applied to a patient. This created a stable gel column between the

patient's skin and the electrode's snap conductor, insuring accurate monitoring. The '346 patent also included a cover to protect the gel pad during storage.

The '346 patent enjoyed immediate and substantial commercial success. In the last quarter of 1970, NDM sold a quarter million of the ready-to-use electrodes. In 1973, NDM sold 18 million electrodes; by 1976, when this action was tried, NDM had annual sales of thirty million electrodes.

In 1973, NDM brought this action against Hayes Products for patent infringement.[2] Hayes Products counterclaimed, seeking a declaration that NDM's patents were invalid for obviousness.

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[2] NDM claimed infringement of four patents: the '807 patent (U.S. Patent No. 3,696,807), the '346 Patent (U.S. Patent No. 3,701,346), and two continuations of the '807 patent and 3,820,531). NDM concedes in this appeal that the validity of the continuation patents hinges on the validity of the '807 patent. Accordingly, discussion of the additional claims of the continuation patents is unnecessary. NDM

(Footnote 2 continued)

had limited its action to claims 15 and 17 of the '807 patent and claims 1 and 8 of the '346 patent.

Claims 15 and 17 of the '807 patent read as follows:

"15. In a medical electrode, a low profile non-conducting, relatively rigid, collapse resistant cup member having a base and a rim, apertured elastic sheet means connected to said cup member overlying said rim, and adhesive on the lower surface of said sheet means adjacent and in surrounding relation to said rim, a snap fastener projecting through said base and supported by said base remote from said rim, said snap fastener projecting through an aperture in said sheet means, and a removable protective cover for said adhesive.

"17. The medical electrode of claim 15 wherein said snap fastener has interfitting parts holding said cup member and said sheet means in assembled relation."

Claims 1 and 8 of the '346 patent read as follows:

"1. A medical electrode of the type adapted to be adhered to the skin and having means defining a cavity opening to the skin and a conductive member of the base of the cavity, wherein the improvement comprises a pad of resilient cellular material loaded with electrolyte and substantially filling said cavity, said pad having a thickness greater than the depth of said cavity whereupon said pad projects outwardly of

(Footnote 2 continued)
said cavity when said electrode is stored and is compressed into said cavity when said electrode is adhered to the skin whereupon said pad is held against movement within said cavity during use of the electrode, and a removable covering for said pad when stored, said covering comprising sheet material having a raised portion overlying said pad and accommodating said greater thickness of said pad.

"8. A medical electrode for use on the skin including an inverted cup member; a flexible elastic sheet overlying and surrounding said cup member; an adhesive layer on the same side of said elastic sheet as said cup member; means securing said elastic sheet to said cup member including an electrically conductive member projecting through the base of said cup member adapted to be electrically connected to an external electrically responsive member; and a pad of resilient cellular material soaked with electrode jelly located in and substantially filling the interior of said cup member, said pad having a thickness exceeding the depth of said cup member whereby said pad is compressed between said electrically conductive member and the skin of a subject to which said elastic sheet is applied, whereby said pad is held in a substantially fixed position during use of the electrode, and a removable covering to protect said pad prior to use of said electrode, said protective covering comprising sheet material and having a raised portion overlying said pad and accommodating the thickness of said pad which exceeds the depth of said cup member."

The district court evaluated Hayes products' assertion of obviousness[3] under the criteria described in Graham v. John Deere Co., 383 U.S. 1, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966). It used ten references to define the scope and content of the relevant prior art.[4] Five of the refer-

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[3] "A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

4 The prior art considered by the district court were the following:

(1) Baum et al, U.S. Patent No. 3,187,745;
(2) Berman et al, U.S. Patent No. 3,085,577;
(3) Tatoian, U.S. Patent No. 3,587,565;
(4) Phipps et al, U.S. Patent No. 3,170,459;
(5) Edmark, U.S. Patent No. 3,487,827;
(6) NASA publication SP-5054, "NASA Contributions to Bioinstrumentation Systems, A Survey by Weltman et al," 1968, pp. 15-24;
(7) Devices, Inc. electrode (Exh. A-10);
(8) IMI electrode and brochure (Exh. A-11 and A-33);
(9) "Which Disposable Chest Electrode?", P.J.B. Hubner; British Medical Journal, 3, pp. 507-510

ences,[5] had not been before the patent examiners when the '807 and '346 patents were granted.

After reviewing all the references before it, the district court invalidated the patents on the grounds of obviousness. NDM appealed.

The Presumption of Validity.

1. Patents issued by the U.S. Patent Office are presumed valid. 35 U.S.C. § 282. This presumption dissipates, however, by a showing that pertinent prior art was not cited to the patent examiners. Hewlett-Packard Company v. Tel-Design, Inc., 460 F.2d 625,628-629 (9th Cir. 1972);

(footnote 4 continued)

(10) "A Press-Stud Electrode for Continuous Monitoring of the Electrocardiogram", D.C. Fluck and P.A. Burgess, The Lancet, Vol. I, p. 1405 (June 25, 1966).

[5] The patent examiners did not consider the prior art listed as 6-10, note 4, supra.

Ceco Corp. v. Bliss & Laughlin Industries, Inc., 557 F.2d 687, 691 (9th Cir. 1977).[6] Prior art is pertinent if it discloses something not disclosed by the other prior art; in other words, it may not be cumulative. Speed Shore Co. v. Denda, 605 F.2d 469, 471 (9th Cir. 1979).

NDM argues that the trial court improperly denied its patents the benefit of the presumption. NDM concedes that five pieces or prior art were not considered by the patent examiners. It

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[6] In several circuits "even one [pertinent] prior art reference not cited to the examiner overcomes the presumption [of the patent's validity]." Turzillo v. P & Z Mergentime, 532 F.2d 1393, 1399 (D.C.Cir.), cert. denied, 429 U.S. 897, 97 S.Ct. 260, 50 L.Ed.2d 181 (1976); Republic Industries, Inc. v. Schlage Lock Co., 592 F.2d 963, 972-973 (7th Cir. 1979). While no Ninth Circuit case expresses so strict a rule, the existence of "some" pertinent prior art references not cited to the examiner destroys the presumption. Ceco Corp. v. Bliss & Laughlin Industries, Inc., 557 F.2d 687, 691 (9th Cir. 1977).

argues, however, that the "prior pertinent art not considered" exception should not invalidate the statutory presumption because four pieces of the prior art were not pertinent and the other was inadmissible. NDM's argument is not convincing.

2. As a preliminary matter, we note that the district court's failure to make an express finding that the statutory presumption had been overcome was not prejudicial error. Hewlett-Packard Company v. Tel-Design, Inc., supra, 460 F.2d at 628.

The district court correctly believed that the two British articles[7] describing a "Devices Electrode" were prior pertinent art not considered by the patent examiners. The Devices Electrode, described by the British Publications, had a

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[7] See numbers 9 and 10 in note 4, supra.

snap fastener remote from the rim of the cup member of the electrode, projecting through and supported by the base of the cup member.[8] Yet, during the prosecution of the '807 patent, NDM's attorney stated the following to the examiner:

> ". . . it is submitted that there is no teaching in . . . [the] prior art of record that the snap fastner be remote from the mouth or rim of the cup member, or that the snap fastner project through and be supported by the base of the cup member." (EXH. A-5 p. 53).

Thus, these British articles, which appeared before the '807 patent was issued and were not before the patent examiners,

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[8] NDM contends that the rim of The Devices electrode is wider and flatter than the rim of the '807. NDM argues that '807 is more easily attachable to rounded surfaces like human skin. This argument goes to the significance of the difference between the prior art and the '807 patent, not to the pertinence of the British publications. To the extent that NDM argues that Devices teaches cumulative learning, it makes a conslusory statement, and no more.

were pertinent prior art. They were not cumulative in describing an electrode with a snap fastener remote from the rim.

3. Therefore, substantial evidence exists for the trial court to have denied NDFM the benefit of the presumption. The presumption was overcome by prior pertinent art not before the patent examiners.

Obviousness.

4. Although obviousness is a legal determination, it is based on a three part factual test set forth in the landmark case of Graham v. John Deere, Co., 383 U.S. 1, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966). The trial court must determine (1) the scope and content of the prior art, (2) ascertain the differences between the prior art and the claimed invention, and (3) measure their differences by the level of ordinary skill possessed by a person familiar with the pertinent art. Relevant subconsiderations include the commercial success of the

invention, the extent to which it resolved long-felt needs, and the difficulty of the problem solved by the invention.

5. The factual findings underlying the "obviousness" determination are reviewed under the Rule 52(a) standard. Photo Electronics Corp. v. England, 581 F.2d 772, 776 (9th Cir. 1978). Unless the findings are clearly erroneous we must sustain them. The district court's factual findings support its conclusion that NDM's patent was obvious and are not clearly erroneous.

Scope and Content of the Prior Art.

Of the ten separate pieces of prior art before the district court,[9] five had not been before the patent examiners.[10] NDM contends that the Devices, Inc. electrode was improperly admitted as

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[9] See note 4, supra.

[10] See note 5, supra.

prior art. It argues that the electrode was inadmissible under 35 U.S.C. § 103 to show obviousness because it was not prior art within the meaning of 35 U.S.C. § 102. The Devices, Inc. electrode apparently was not "in public use or on sale in this country" as required by § 102(b). NDM argues that § is the exclusive referent for ascertaining prior art under § 103. 6. We need not decide the very thorny question of the relationship between § 102 and § 103 and the extent to which prior art under one may serve as prior art under the other.[11] The trial court correctly admitted as prior art the British publications in which the Devices, Inc. electrode was described.[12] The district court did not need the electrode itself to

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[11] See generally, Chisum, Sources of Prior Art in Patent Law, 52 Wash.L.Rev. 1 (1976).

[12] See numbers 9 and 10 in note 4, supra.

compare the Devices, Inc.'s electrodes with NDM's electrodes. Therefor, the admission of the Devices, Inc. electrode as part of the prior art did not prejudice NDM.

The Level of Skill in the Art.

NDM does not contend that the district court's finding on this issue was clearly erroneous. We thus may move on to consider the heart of this lawsuit.

The Differences Between the Prior Art and the NDM Patents

'807 Patent

The trial court invalidated the '807 patent on grounds of obviousness after careful comparison of the '807 and the prior art. In Finding of Fact 49, the trial court found that the

> "Berman et al Patent No. 3,545,432, Tatoian Patent No. 3,587,565 and the IMI brochure, all recognized the use of a resilient foam pad in combination with a cup electrode to hold the cup member of an electrode against the skin, the same purpose and function stated in the specification of the '807 [patent's elastic sheet] . . . ."

And in Finding of Fact 55, it found that

> "Prior to the alleged invention of the '807 patent it was known to use a snap fastener having interfitting parts not only to serve as the conductor element of the electrode but to, at the same time, clamp various elements of the electrode together." [The Edmark and Berman patents in particular disclosed this.]

The court also cited the Devices, Inc. electrode description in the British publications in Finding of Fact 56 as disclosing the obviousness of a snap fastener. Substantial evidence permitted the court to find the patents obvious.

The British publications relating to the Devices, Inc. electrode disclose a (1) low-profile, non-conductive, relatively rigid, collapse-resistant cup having a base and a rim;[13] (2) a sheet means connected to the cup and surrounding the rim;[14]

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[13] See the plastic cup 2 described in number 10 note 4, supra.

[14] See the Beckman double-baked sticky ring 6 described in number 120, note 4, supra.

(3) a snap fastener projecting through the base of the cup and supported by the base of the cup remote from the rim;[15] and (4) a removable protective cover for the adhesive.[16] These four characteristics were claimed in the '807 patent.[17]

In addition, the IMI brochure, the Berman '432 and the Tatoian '565 disclose the use of adhesive-backed foam pads to hold the electrode in place. No different result is obtained by the use of the '807's "elastic sheet."

On the basis of this evidence, the district court could have concluded that '807 patent was obvious to one skilled in the art.

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15 See the press stud electrode 4 described in number 10, note 4, supra.

16 See the release paper on the lower side of the Beckman double-backed sticked disc described in number 10, note 4, supra.

17 See claim 15 of the '807 patent, note 2, supra.

The patentable differences between the '807 and '346 patents were the presence and configuration of the gel-soaked pad in the cup member and the presence and configuration of the cover for the gel-soaked pad.

In Findings of Fact 61 and 62, the district court held that the existence and use of a gel-soaked pad in the cup of a medical electrode, and the existence and use of a protective cup over such a gel-soaked pad were disclosed by the Baum et al patent No. 3,187,745 and the NASA publication.[18]

NDM does not dispute that the "concept of a pre-gelled, disposable, surface-mounted biomedical electrode" existed

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[18] In Finding of Fact 63, the district court improperly took judicial notive of the obviousness of the patentable differences between the prior art and the '346 patent. Because the finding was not necessary to the court's decision, the error was harmless.

prior to the '346 patent. The Baum '745 and NASA publication disclose that. NDM contends instead that "an electrode having a resilient pad which oversized during storage and is then compressed upon application to a subject is not disclosed in any of the art of record." This is what NDM's attorney argued before the patent office to distinguish the claims of the '346 patent from the Baum '745.

Essentially, the only difference between the '346 patent and the Baum '745 patent is in the protective cover for the pad. The Baum '745 compresses all of the gel to the level of the rim of the cup. In the '346 patent, on the other hand, the dimple in the cover compresses part of the gel below the level of the rim of the cup permitting the rest of the gel pad to remain above that level.

The district court believed this difference to be obvious. Substantial

evidence supports the findings. The NASA SP-5054 publication discloses an electrode having an electrolyte-soaked gel pad with a thickness greater than the cup. The gel pad is stored in an uncompressed state but is compressed partially into the cup when the helmet incorporating the electrode is fitted to the astronaut's head and the electrode touches the scalp.

Even without this disclosure, the court could have found the '346 patent obvious. There is no functional difference between the Baum '745 and the '346 once the protective cover of each is removed. It may well be as NDM argues that the '346 was an improvement[19] over the '745, achieving a more stable gel column when applied to the skin. But "[i]n applying section 103 ... the test is not whether the object is an improvement in the art; ..." but whether an

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[19] The trial court found the improvement to be substantial.

improvement is obvious to one skilled in the art. Reinke Mfg. Co., Inc. v. Sidney Mfg. Corp., 594 F.2d 644, 646 (8th Cir. 1979). "'[A]n improvement which is obvious ... is not entitled to protection.'" Id. The record supports the trial court's conclusion that the '346 patent was obvious to one skilled in the art.

Secondary Considerations of Nonobviousness.

[7] NDM points to the considerable commercial success of its electrode, arguing that the devices resolved a long-standing problem in cardiac monitoring. These factors are relevant to determining patentability, Graham v. John Deere Co., 383 U.S. at 12, 86 S.Ct. at 691, but they are of secondary importance. Id. at 18, 86 S.Ct. at 694. Their consideration is permissible, not required, and their presence or absence is not alone determinative of obviousness. Id., see also, Penn

Intern Industries v. Pennington Corp., 583 F.2d 1078, 1081 (9th Cir. 1978). Indeed, where patents are obvious, they cannot be saved from invalidity by a resort to such secondary considerations. Jeddeloh Brothers Swee Mills, Inc. v. Coe Manufacturing Co., 375 F.2d 85, 91 (9th Cir.), cert. denied, 389 U.S. 823, 88 S.Ct. 57, 19 L.Ed.2d 76 (1967).

The district court in this case had substantial evidence to find the '807 and '346 patents obvious. It was not bound by the secondary consideration alluded to by NDM.

Synergism: '807 and '346 Patents.

[8] The synergistic test of patentability of combination devices derives from A. & P. Tea Co. v. Supermarket Corp., 340 U.S. 147, 71 S.Ct. 127, 95 L.Ed. 162 (1950), reh. denied, 340 U.S. 918, 71 S.Ct. 349, 95 L.Ed. 663 (1951). Patents may be

issued for inventions which combine elements existing in the prior art if the result is "unusual or surprising." Id. at 152, 71 S.Ct. at 130; see also, Photo Electronics Corp. v. England, 581 F.2d 772, 775 (9th Cir. 1978). "[This test] is not inconsistent with, but merely in application of, the general rule stated in § 103...." Reeves Instrument Corp. v. Beckman Instruments, Inc., 444 F.2d 263, 271 (9th Cir.), cert. denied, 404 U.S. 951, 92 S.Ct. 283, 30 L.Ed. 2d 268 (1971). Cf Republic Industries, Inc. v. Schlage Lock Co., 592 F.2d 963 (7th Cir. 1979), Plastic Container Corp. v. Continental Plastics, 607 F.2d 885 (10th Cir. 1979), cert. denied, 444 U.S. 1018, 100 S.Ct. 672, 62 L.Ed.2d 648 (1980). (The Seventh and Tenth Circuits recently rejected synergism as a separate test of patentability because of its inconsistency with § 103 analysis.) But the test is a much more stringent rule

of patentability than the usual § 103 test, because "non-obviousness is less likely to occur in combination patents, ..." Reeves Instrument Corp. v. Beckman Instruments, Inc., supra, 444 F.2d at 271, which are simply amalgams of old elements. See also, Palmer v. Orthokinetics, Inc., 611 F.2d 316, 323 (9th Cir. 1980).

[9] If the trial court had substantial evidence to find the '807 and '346 patents obvious, it also had sufficient evidence to find them lacking in synergism. Schimizzi v. Chrysler Corp., 462 F.Supp. 630, 639 (S.D.N.Y.1978); see also, Bird Provision Co. v. Owens Country Sausage, Inc., 568 F.2d 369, 378 (5th Cir. 1978) (no need to consider synergism were patent invalid for novelty and obviousness). If the test for synergism is more strict than the usual rule of § 103, and it is, then the district court could not have found the

patents invalid for obviousness, but valid for evidencing synergism.[20] On the record before us, we have concluded that the district court could have found the NDM patents invalid for obviousness. Therefore, this conclusion subsumes within it a finding that the patents lack synergism.

Affirmed.

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[20] The trial court found that the stable gel column created by the '346 patent produced "surprising and unexpected" improvements in offset voltage readings. In Finding to Fact 58, the court expressly found that the '807 patent lacked synergism.

APPENDIX B

NDM CORPORATION, Plaintiff, HAYES PRODUCTS, INC. and JOSEPH H. JOHNSON, Defendants.	) Civil Action No. 124-73C2)) FINDINGS OF FACT) AND CONCLUSIONS) OF LAW))

A. NATURE OF THE ACTION AND JURISDICTION

1. Initially this was an action for infringement of four patents, three of which have Roman Szpur named as inventor; namely, Patent 3,696,807, Patent 3, 713, 435, and Patent 3,820,531; and the fourth of which, Patent 3,701,346, has Charles T. Patrick and Roman Szpur named as joint inventors. By the time of the pretrial order, plaintiff limited the infringement action to claims 15 and 17 of Patent 3,696,807 and claims 1 and 8 of Patent 3,701,346.

2. Defendants filed a declaratory judgment counterclaim for invalidity,

noninfringement and unenforceability of all four patents, and although plaintiff no longer contends infringement in its action of any of the claims of the '435 and '531 patents, defendants still assert invalidity and unenforceability of these two continuation patents, in addition to asserting noninfringement, invalidity and unenforceability of claims 15 and 17 of the '807 patent and claims 1 and 8 of the '346 patent.

3. Trial of this action was held on November 1-5, 1976, on the issues of infringement and validity. Trial on the issue of damages has been deferred until after determination of the infringement and validity issues. Trial of the issue of defendant Joseph H. Johnson's personal liability for infringing acts performed by Hayes Products., Inc., has also been deferred.

4. Jurisdiction and venue of the Court are invoked under §§1338(a), 1400(b) and 2201 of Title 28 U.S.C.A. and §§271 and 281 of Title 35 U.S.C.A. The jurisdiction and venue of the Court are not disputed.

B. THE PARTIES

5. Ohio Sealer and Chemical Corporation, an Ohio corporation, was incorporated in 1953. Bionetics, Inc., an Ohio corporation, was incorporated in November 1968. Its name was changed to Bionetics Electrochem, Inc., and later back to Bionetics, Inc. The original NDM Corporation, an Ohio corporation, was incorporated in July 1970, and became the sales arm for electrodes manufactured by Bionetics, Inc. In March 1972, Bionetics, Inc. and the original NDM Corporation were merged into Ohio Sealer and Chemical Corporation, which became the surviving corporation and the name of this surviving corporation was

changed to NDM Corporation which is the present plaintiff.

6. Bionetics Inc. was formed with one of the purposes of the corporation being the development, manufacture and sale of a medical electrode. The first officers of Bionetics, Inc. were: Richard F. Glennon, president and treasurer; John Kater, vice-president; and Horace Worman, secretary. Roger Ekbom became president of Bionetics, Inc. in 1970.

7. Defendant, Hayes Products, Inc., is a corporation of the State of Washington formed in October 1971, and having a principal place of business at 8500 Perimeter Road South, Seattle, Washington 98108.

8. Defendant, Joseph H. Johnson, is an individual residing in Seattle, Washington, and is President of defendant Hayes Products, Inc. Prior to the formation of

Hayes Products, Inc., Joseph H. Johnson manufactured and sold electrodes under the name Hayes Technical.

C. DEVELOPMENT OF PLAINTIFF'S ELECTRODE

9. John Kater became interested in developing a disposable "dry" electrode shortly after Bionetics, Inc. was in business, the electrode to be activated by moisture in the patient's skin and not require the application of electrolyte gel prior to use.

10. Robert Wightman worked under Roger Ekbom in 1966 and later went into business for himself in Pennsylvania as a distributor of medical equipment. At least as early as January 1969, he was a distributor of the "Derma-Circ" electrode manufactured by Physio-Control Corporation. Wightman had connections for conducting clinical evaluations of medical electrodes.

11. During the early part of October 1969, Robert Wightman conducted clinical

tests of prototype dry electrodes made by Kater. These electrodes did not perform well as is reported by Wightman by letter to Kater of October 8, 1969, and so Ekbom and Glennon then made the decision to retreat from the dry electrode objective to a disposable wet electrode by adding a plastic screen disc to Kater's dry electrode to which electrode gel would be applied at the time the electrode was to be placed on a patient. Such a screen was in use at that time on the Derma-Circ electrodes distributed by Wightman.

12. Roman Szpur has a background in research and physics derived from 21 years with the United States Air Force (until 1963), and his own research and development company, the Szpur Corporation, started in 1964. Szpur's electrode activities with Bionetics, Inc., commenced in late 1969.

13. On October 10, 1969, Glennon had a meeting with Roman Szpur in which he

showed Szpur the Derma-Circ electrode with the screen and discussed with him the possibility of taking the dry electrode made by John Kater and putting a screen on its face to make it receptive to a gel, reducing the area that had Ag/AgCl on it, and increasing the pure adhesive area by either increasing the diameter of the porous adhesive tape or by leaving that diameter as it was and increasing the diameter of the overlay vinyl tape so that it extended one-half inch beyond the edge of the porous paper. This was Szpur's first knowledge of the concept of a "wet" electrode. At that meeting of October 10, 1969, Glennon also reached a verbal agreement with Szpur on the development of a machine to automatically manufacture for Bionetics, Inc. an electrode to be developed by Kater.

14. Prior to October 1969, Szpur had no background or exposure to medical electrodes.

15. On October 29, 1969, Kater mailed to Glennon prototypes of a wet electrode and a letter describing the construction thereof as comprising: (1) porous 3M tape; (2) non-porous tape covering the porous tape; (3) "rigid disc, paper or plastic" over the non-porous tape; (4) silver plated snap fastener holding the first three items together; (5) plastic screen stuck to the underside of the 3M tape; (6) Ag/AgCl slurry painted over screen, and covering the snap fastener, adhesive and screen; and (7) release paper. Kater stated that, with the stiff disc, the electrode was better than the Derma-Circ because it had better contact impedance and lack of motion artifact.

16. In his letter to Glennon of October 29, 1969, Kater stated: "As for wet electrodes, they should preferably have a rigid backing or rigid cup-shaped gel

cavity." If there was any novelty in the use of a rigid backing or clamping washer, or a rigid cup-shaped cavity in the electrode having a snap fastener disclosed and claimed in the '807 patent, it was the contribution of Kater and not Szpur.

17. On October 23, 1969, Szpur gave Glennon a written quotation for a machine to make a wet electrode in which an electrode construction sequence was given. There was no mention in the quotation of a rigid backing disc or a cup. Szpur was not contracted to design an electrode.

18. On November 4, 1969, Kater sent a letter to Glennon disclosing a wet electrode with an adhesive-coated foam pad for adhering the electrode to the skin having a central gel cavity formed by a center opening in the pad closed at one end by a semi-rigid support disc bonded to the foam pad. A snap fastener passed through

the support disc and a screen was seated in the center opening of the foam pad against the snap fastener. In the letter Kater mentioned that he had used a piece of packaging foam for the electrode and that 3M made a foam with medical grade adhesive on one side. (Kater made a model of the electrode disclosed in his letter.) A copy of the letter was given to Talman Dybvig, then patent counsel for plaintiff and Charles Patrick, then vice-president of plaintiff. At trial Patrick identified the 3M foam as being an open cell foam.

19. On November 7, 1969, Roman Szpur sent a note to Glennon enclosing Drawing No. SCI-109002, dated November 6, 1969 showing an electrode with a non-porous adhesive-coated sponge pad having a snap fastener clamped at the center, a filter screen, a small perforated porous sponge over the filter screen, and a slit release

paper. This was the first written disclosure made by Szpur with respect to an electrode having a sponge pad. It occurred after he received prototype electrodes of a similar type from John Kater.

20. On or about November 21 and 25, 1969, Roman Szpur made Drawing Nos. SCI-109003 and SCI-109004, respectively, of a modified electrode with a foam pad not having any filter screen of the type shown in his prior Drawing No. SCI-109002, and showing a porous plastic disc between a non-porous plastic disc and a non-split paper protective cover serving as a release paper. The porous plastic disc was detailed by Szpur on or about November 20, 1969, in Drawing No. SCI-109005 and had a recessed central portion for gel as well as being perforated.

21. Drawing No. SCI-109010 dated December 26, 1969, was the first known

drawing of an electrode made by Roman Szpur embodying the invention disclosed and claimed in Szpur Patent No. 3,696,807.

22. On February 4, 1970, Roman Szpur met with Talman Dybvig, Richard Glennon, and others, at the Dayton Country Club. Following this meeting Szpur had a memorandum accurately summarizing the parts of the meeting having particular reference to him. During that meeting Dybvig raised questions about the patentability of Szpur's electrode, and Szpur's response was that "the following two points are strong in the proposed electrode":

> "(1) the main disc made from thick soft and stretchable material, which behaves like a rubber or rubber-like material, and (2) a spring-like effect generated by the main disc material, specifically, pressure is applied (gently) around the cup, which holds electrolite, so that when the body, skin, etc., is making a move the spring-like network around the cup is able to follow the contour of the body, continuously keeping gentle pressure between the cup and the body, skin, etc."

23. The medical electrode as claimed in the '807 patent was conceived by Roman Szpur in December, 1969. On February 12, 1970, Roman Szpur signed the patent application which ultimately issued as U.S. Patent No. 3,696,807, and also signed an Assignment document in favor of Bionetics Electrochem, Inc. The Szpur application was filed on February 13, 1970, as application Serial No. 11,208. The assignment records of the U.S. Patent and Trademark Office show a chain of title from Bionetics Electochem, Inc. to plaintiff.

24. A limited number of electrodes of the type shown in the '807 patent were sold in about March, 1970, by Bionetics, Inc. These electrodes, as described in the patent, included a collapse resistant cup member having an adhesive coated elastic foam sheet connected to the cup by means of a conductive snap fastener, but these electrodes were not "pre-gelled" electrodes since electrolyte gel had to be added to the cup of the electrodes before application to a patient.

25. In May, 1970, Patrick made samples for Baxter Laboratories of electrodes like that shown in Fig. 2 of the Szpur '807 patent. These samples were pre-gelled, but did not have a gel pad, and the cups filled with electrolyte gel were covered with Saran Wrap. The samples were wrapped in aluminum foil and cables were preattached.

26. The alleged medical electrode invention described and claimed in Patrick et al Patent No. 3,701,346 was conceived in late May or early June 1970, and patent application serial No. 103,498, which later issued as said patent, was filed on January 4, 1971, in the names of Roman Szpur and Charles T. Patrick. The assignment records of the U.S. Patent and Trademark Office show a chain of title from Szpur and Patrick to Plaintiff.

27. The gel pad covers of the first electrodes offered for sale by plaintiff

were vacuum formed from a butyrate plastic. The primary function of the cover was to protect the oversized gel pad so that it would not be crushed or damaged in the course of shipment and storage. The cover also included an inward projection or "dimple" which assisted in holding the gel pad in place during shipment, but was not a necessary or critical element of the Patrick-Szpur invention.

28. Plaintiff filed the first Szpur continuation application on June 5, 1972. The application contained the five claims present in the first Szpur continuation patent No. 3,713,435 without any modification. The claims were allowed by the Examiner without argument by preliminary notice on October 12, 1972, and by notice of allowance dated October 27, 1972. The issue fee was paid on November 13, 1972, and the patent issued on January 30, 1973.

29. Plaintiff filed a second Szpur continuation application the same day that the first Szpur continuation patent issued (January 30, 1973). Four claims were initially presented in the second continuation, the broadest of which was claim 20.

30. The Examiner, after amendments to the four claims originally submitted in the second Szpur continuation appliation and after a telephone interview between the Examiner and plaintiff's attorney on January 17, 1974, allowed the claims to issue in the form appearing in the second Szpur continuation patent No. 3,820,531 on June 28, 1974.

D. THE SCOPE AND CONTENT OF THE PRIOR ART

31. The art to which the subject matter of the patents in suit pertains is eletrodes employed to detect bioelectric events including electrodes used for electrocardiography (ECG) and electroencephalography (EEG).

32. In the early 1960's, there was little if any long term monitoring of patients being carried out in hospitals. The electrodes that were used when electrocardiographic monitoring was carried out were generally of the flat metal plate type fastened to the arm and leg of a patient, usually by some elastic strap encircling the arm or leg. Before the plate was attached to the arm or leg, a small amount of an electrolyte, at that time called electrode paste was placed on the surface of the skin. This metal plate electrode, which was in general use in the early 1960's, was substantially the same type of electrode which had been developed in about 1912. These metal plate electrodes were inconvenient in that they required time to attach and did not necessarily guarantee a good contact.

33. Also commonly in use in hospitals of the 1960-65 period were needle

electrodes. This type of electrode was often used for what was then considered to be long-term monitoring, i.e., up to a six-hour period, during open heart surgery or like operations. At the present time, long-term monitoring has come to mean monitoring for four to six days. Electrodes such a the metal plate electrodes discussed above were normally used for only a few minutes at a time at the most. The use of needle electrodes had advantages in that the dry, relatively non-conductive surface of the human skin could be bypassed, thus producing quality electrical performance. However, the need to puncture the patient's skin and the obvious patient aversion to having needles stuck in him made these electrodes less than satisfactory for long-term cardiac monitoring.

34. Suction cup electrodes were also in use in hospitals prior to the inventions

of the patents here in suit. Suction cup electrodes were attached to the skin by squeezing the bulb, thereby creating a partial vacuum when the bulb began to expand. These electrodes were satisfactory for recording an electrocardiogram for a short period, such as would be common during a physical examination, but were not satisfactory for long term monitoring due to their tendency to fall off as the partial vacuum was lost.

35. Particularly after the 1965-66 period, reuseable electrodes of the type including a metallic plate mounted in a housing, and adapted to make electrical contact through an electrolyte, came into use. In some cases, electrodes of this type were simply attached to the patient and held in place by adhesive tape. Alternatively, double-sided adhesive discs were attached to the survace of the electrode adapted to contact the skin of the

patient, and then a rather precise amount of electrode jelly was placed in the housing of the electrode adjacent the metal plate. If too much gel was added to the electrode, using either the adhesive tape or the double-sided adhesive disc, the gel would spread out and attack the sticking qualities of the tape and cause the electrode to come loose. On the other hand, if too little gel was added to the electrode, the electrical contact would be poor because of the lack of coverage of the entire surface of the contact with gel.

36. Reuseable electrodes were not only time consuming and difficult to apply properly, but also required thorough cleaning and sterilizing between patient uses. Further, routine refurbishment of these electrodes was normally required once every 24 hours.

37. Disposable electrodes also had come into use by the late 1960's, perhaps

the first being a Bandaid-type electrode comprising a snap conductor mounted on a piece of adhesive tape. At the time of use, a precise amount of gel was placed on the conductive member of the electrode and the electrode attached to a patient's skin. As with the reuseable electrodes, the addition of an improper amount of gel to the electrode at the time it was applied to a patient could seriously compromise either the life or the electrical performance of the electrode. Direct contact between the metallic conductor and the patient's skin is possible in this type of electrode but not desired as such direct contact between the conductive member and the patient's skin produces unwanted artifacts or "noise" in the electrocardiogram trace.

38. Many other disposable electrodes were being offered in the marketplace in

the late 1960's, these electrodes having a wide variety of materials. Some of these electrodes were held on a patient by means of adhesive tape and others by means of double-sided adhesive discs. Some of the electrodes included conductive members formed in the shape of a snap; others included conductive members with permanently affixed wires adapted to run to a monitor. Some of these electrodes included a piece of sponge mounted over the conductor to hold electrolyte which was added to the electrode at the time of use; others included conductive or non-conductive screens to receive gel. In still others, gel was placed directly on the conductive member.

39. The most pertinent prior patents, publications and physical exhibits relative to the issues in this law suit comprise the following:

(a) Baum et al, U.S. Patent No. 3,187,745;

(b) Berman et al, U.S. Patent No. 3,085,577;

(c) Tatoian, U.S. Patent No.3,587,565;

(d) Phipps et al, U.S. Patent No. 3,170,459;

(e) Edmark, U.S. Patent No. 3,587,565;

(f) NASA publication SP-5054, "NASA Contributions to Bioinstrumentation Systems, A Survey by Weltman et al," 1968, pp. 15-24;

(g) Devices, Inc. electrode (Exh. A-10);

(h) IMI electrode and brochure (Exh. A-11 and A-33).

(i) "Which Disposable Chest Electrode?" P.J.B. Hubner; British Medical Journal, 3, pp. 507-510 (August, 1969);

(j) "A Press-Stud Electrode for

Continuous Monitoring of the Electrocardiogram", D.C. Fluck and P.A. Burgess, The Lancet, Vol. I, p. 1405 (June 25, 1966).

40. Publications available to the public prior to the alleged inventions described in the '807 patent, the first and second continuations thereof (patent Nos. 3,713,435 and 3,820,531) and the '346 patent disclosed the following:

(1) The concept of a disposable surface-mounted biomedical electrode for use with patient-monitoring equipment: Edmark, Patent No. 3,487,827, col. 1, lines 56-60; Darling, Patent No. 3,340,868, col. 1, lines 21-32; Mason, Patent No. 3,464,404, col. 1, lines 34-37; Mason, Patent No. 3,518,984, col. 1, lines 34-37; and Tatoian, Patent No. 3,587,565, col. 1, lines 31-36.

(2) The concept of a pre-gelled, disposable surface-mounted biomedical electrode: Edmark, Patent No. 3,487,827, col. 1, lines 51-60; NASA Tech Brief, number 66-10118; Baum et al Patent No. 3,187,746, col. 2, lines 13-23; and NASA SP-5054, p. 21.

41. Pre-gelled, disposable medical electrodes for cardiac monitoring were commercially available and on the market before the alleged inventions described and claimed in the '807 patent or '346 patent were conceived. One such electrode was known as the Elema-Schonander electrode, and it was described, its cost and manufacturer given, and its performance summarized in the British Medical Journal publication dated August, 1969. John Kater read about the Elema-Schonander electrode in a technical paper which he submitted to Charles Patrick. The British Medical Journal article indicated that the pre-

gelled disposable Elema-Schonander electrodes "were clearly superior to other types, as 70% of the electrodes pairs had impedance values of less than 5 K/ohms" and "were the most efficient".

42. All of the elements making up the surface-mounted medical electrodes described and claimed in the '807 patent, the first and second continuations thereof (3,713,435 and 3,820,531) and the '346 patent were disclosed in publications available to the public prior to the alleged inventions described in the patents in suit. The elements known included:

(1) the use of a collapse-resistant plastic cup holding a quantity of conductive gel, the cup having an electrode element in its base isolated from the skin of a patient: Berman 3,545,432; Baum et al 3,187,745; Day et al 3,420,223; Domingues 3,496,929; Mason 3,464,404 and 3,518,984;

Devices electrode (Exh. A-10); The Lancet publication; IMI electrode (Exh. A-11); B-D electrode (Exh. A-31); and NASA Tech Brief 66-10118.

(2) the use of a conventional snap fastener as the conductive element in a surface mounted medical electrode: Devices electrode, The Lancet publication; British Medical Journal publication; Edmark 3,487,827; Berman et al 3,085,577; Red Dot electrode (Exh. A-36); and Derma-Circ electrode (Exh. A-35).

(3) the use of an elastic foam sheet means having an adhesive on its lower surface for adhering the foam sheet to the skin of a patient and for holding the electrode against the skin: IMI brochure (Exh. A-33); Berman 3,545,432; Tatoian 3,587,565.

(4) the use of a removable protective cover for the adhesive coated on an

elastic foam sheet means to prevent damage to the adhesive during storage: Tatoian 3,587,565; IMI brochure (Exh. A-33).

(5) the use of a resilient cellular pad saturated with an electrolyte gel and placed in a cup member: British Medical Journal publication; Baum et al 3,187,745; Phipps et al 3,170,459.

43. The following combinations of elements making up surface-mounted medical electrodes were disclosed in publications available to the public prior to the alleged inventions described in the '807 patent, the first and second continuations thereof and the '346 patent.

(1) surface-mounted biomedical electrodes having a non-conductive, relatively rigid, collapse-resistant plastic cup member for holding an electrically conductive gel, the rim of the cup member resiliently pressed against the skin to form a seal between the skin and the cup to

prevent escape of the conductive gel by a sheet of elastic foam material overlying and connected to the cup, the elastic foam sheet having an adhesive on its lower surface for adhering the foam sheet to the skin of a patient and for holding the electrode against the skin: Berman, 3,545,432; IMI electrode (Exh. A-11) and brochure (Exh. A-33); and Tatoian 3,587,565.

(2) surface-mounted biomedical electrodes having a cup member with a cavity opening to the skin, an electrically conductive element at the base of the cavity, a pad of resilient cellular material loaded with an electrolyte gel filling the cavity having a thickness greater than the depth of the cavity and a removable protective covering for the pad when stored: Baum et al 3,187,745.

(3) surface-mounted electrodes having an electrical conductor consisting

of interfitting parts pressed together to hold elements making up the electrode in assembled relation: Edmark 3,487,827; Red Dot electrode (Exh. A-36); Derma-Circ electrode (Exh. A-37); and Devices electrode (Exh. A-10).

(4) surface-mounted biomedical electrodes employing a collapse-resistant plastic cup member with an electrically conductive electrode isolated from the skin by an electrically conductive paste held within the cavity of the cup member: Berman 3,545,432; Baum et al 3,187,745; Day et al 3,420,223; Domingues 3,496,929; Mason 3,158,984; Mason 3,464,404; British Medical Journal and The Lancet publications; Devices, Inc. electrode (Exh. A-10); IMI electrode (Exh. A-11); Dispos-el electrode of B-D (Exh. A-44); and NASA Tech Brief 66-10118.

(5) surface-mounted biomedical

electrodes employing a non-conductive, relatively rigid, collapse-resistant cup member having a base and a rim with an electrically conductive snap fastener projecting through the base of the cup and supported by the base remote from the rim of the cup, the cup holding either a conductive electrolyte gel or an electrolyte gel-impregnated foam pad: British Medical Journal publication; The Lancet publication; and the Devices electrode (Exh. A-10).

(6) surface-mounted biomedical electrodes having a cup member with a cavity opening to the skin, an electrically conductive element at the base of the cavity resembling a snap fastener, a sheet of elastic foam material overlying the rim of and connected to the cup, the foam material having an adhesive on its lower surface for adhering the foam sheet to the

skin of a patient and for pressing the rim of the cup against the skin to form a seal between the skin and the cup, and a removable protective cover for the adhesive: Tatoian 3,587,565.

44. Each of the elements making up the medical electrodes described and claimed in the '807 patent, the first and second continuation patents thereof and the '346 patent function in the same manner as the same respective elements disclosed in publications available to the public prior to the alleged inventions described in the patents in suit:

(1) The snap fasteners described in Edmark patent No. 3,487,872; the Derma-Circ electrode (Exh. A-37); the Ferris Red Dot electrode (Exh. A-36) and Berman et al patent No. 3,085,577, function as the conductive element of the electrode and to clamp the elements of the electrode together in assembled relation in the same

way and for the same purpose as the snap fastener disclosed and claimed in the patents in suit.

(2) The elastic foam sheet material having an adhesive coated on its lower surface, described in the IMI brochure (Exh. A-33), Berman patent No. 3,545,432 and Tatoian patent No. 3,587,565, functions to hold the cup member of those electrodes against the skin of the patient in the same way and for the same purpose as the elastic sheet material described in the patents in suit.

(3) The resilient pads of cellular material saturated with electrolyte gel placed in the cup members of the electrodes described in The Lancet publication, Phipps et al patent No. 3,170,459; and Baum et al patent No. 3,187,745, for maintaining good electrical contact between the metallic conductive element of the electrode and the

skin of the patient, function in the same way and for the same purpose as the saturated pad in the '346 patent.

(4) The protective cover for preventing dryout of the electrolyte gel or gel-saturated pad placed in a cup member in the electrodes described in Baum et al patent No. 3,187,745, NASA Tech Brief 66-10118, NASA SP-5054, Edmark patent No. 3,847,827 and Mason patent No. 3,518,984, function in the same manner as the protective cover in the patent.

E. THE DIFFERENCES BETWEEN THE PRIOR ART AND THE CLAIMS OF THE SZPUR PATENT IN SUIT

45. The configuration of the rim of the cup member of plaintiff's electrode is not defined in claims 15 and 17 of the '807 patent, any of the claims of the '435 and '531 patents, nor in claims 1 and 8 of the '346 patent.

46. The use of "elastic sheet means" to adhere an electrode to the skin of a patient was well known before the invention described and claimed in the '807 patent and the first and second continuations thereof. The IMI brochure describes the use of Reston foam pads to hold the electrode "securely to the skin and allow the skin to move with the electrode,. . ."

47. Berman patent No. 3,545,432 discloses a resilient compressible material having a pressure sensitive adhesive on one side to seal the rim of the cup member of the electrode against the skin.

48. Tatoian patent No. 3,587,565 discloses a foam pad for holding the electrode to the skin with the connection for the monitor lead (analogous to a snap fastener) of Fig. 6 projecting upwardly through a center hole in the pad.

49. Berman et al patent No. 3,545,432,

Tatoian patent No. 3,587,565 and the IMI brochure, all recognized the use of a resilient foam pad in combination with a cup electrode to hold the cup member of an electrode against the skin, the same purpose and function stated in the specification of the '807 patent, col. 4, lines 35-43.

50. There is no different result obtained in the use of an elastic sheet means to hold the cup member of plaintiff's medical electrode against the skin of a patient than was obtained by use of elastic foam pads described in the IMI brochure, Berman patent No. 3,545,432 and Tatoian patent No. 3,587,564 used for the same purpose.

51. The elastic foam material used in the plaintiff's electrode and described and claimed in the patents in suit was a commercial item of manufacture at the time

the alleged invention of the '807 patent was made and was given to Szpur by Patrick.

52. Selection of a known, particular elastic foam material for another known material used as the adhesive carrying member for holding the cup member of a medical electrode against the skin of a patient is within the competence of the person of ordinary skill in the medical electrode art.

53. John Kater, prior to the alleged invention described and claimed in the '807 patent, took a Devices electrode on the market and put a piece of adhesive carrying 3M foam pad over it with the snap fastener of the Devices electrode projecting through the pad for connection to a lead wire, and tested the working of such electrodes on himself. This was an obvious way of adhering this electrode to the skin without having the lead wire connecting to the snap fastener come out underneath the foam pad.

54. The Court finds that claim 15 of the '807 patent, claim 1 of the '435 patent and claim 1 of the '531 patent, which rely in whole or in large part on the elasticity of the "sheet means" for patentability, are invalid as being obvious to one of ordinary skill in the art.

55. Prior to the alleged invention of the '807 patent it was known to use a snap fastener having interfitting parts not only to serve as the conductor element of the electrode but to, at the same time, clamp various elements of the electrode together. Edmark patent No. 3,847,827; the Derma-Circ electrode (Exh. A-37); the Red Dot electrode (Exh. A-36) use a snap fastener having interfitting parts to clamp a flexible adhesive-carrying number and plastic disc together. Berman et al patent No. 3,085,557 uses a snap fastener having interfitting parts to clamp a

flexible adhesive-carrying member 13, the porous absorbent pad 20 and the screen 19 together, a fact not noted by the Exmainer [sic] during prosecution of the '807 patent.

56. The Devices electrode (Exh. A-10) as described in The Lancet and British Medical Journal publications discloses mounting of a snap fastener as a contact element in the base of the cup member of a cup-type medical electrode. Claims 2-5 of the '435 patent substantially read on the Devices electrode (Exh. A-10) and any differences are so slight as to have been obvious to one of ordinary skill in the art.

57. Claim 17 of the '807 patent, dependent on claim 15 thereof, and claims 2-4 of the '531 patent, dependent on claim 1 thereof, are invalid as obvious in view of the Devices electrode (Exh. A-190 and The Lancet and British Medical Journal

publications relating thereo, [sic] and the Edmark, Berman and Tatoian patents.

58. Claims 15 and 17 of the '807 patent and all of the claims of the '435 and '531 patents define obvious combinations of old elements not providing a synergistic effect or any unusual or surprising results.

F. THE DIFFERENCES BETWEEN THE PRIOR ART AND THE CLAIMS OF THE '346 PATENT.

59. The '807 patent discloses but does not claim a pre-gelled electrode and is a prior art reference as to the subject matter claimed in the '346 patent.

60. All of the elements of claim 1 and claim 8 of the '346 patent are disclosed by Fig. 4 of the '807 patent except for the presence and configuration of the gel-soaked pad placed in the cup member and the presence and configuration of the cover for the gel-soaked pad.

61. The use of a gel-soaked sponge or pad in the cup of a medical electrode to stabilize the column of gel in the cup and assure electrical contact of the electrode with the skin of the patient was well known prior to the alleged joint invention described and claimed in the '346 patent: Baum et al patent No. 3,187,745; NASA SP-5054; Phipps et al patent No. 3,170,459; and the British Medical Journal publication.

62. The use of a protective cover over a gel-soaked pad placed in the cup member of a medical electrode to protect the pad from drying out during storage was known prior to the alleged joint invention claimed in the '346 patent. Baum et al patent No. 3,187,745 and NASA. SP-5054.

63. It is only necessary that the Court consider those modifications disclosed in the '346 patent not disclosed in the '807 patent, namely the use of a gel-soaked pad, part of which may extend

out of the cup during storage, with a cover having sufficient height to accommodate the extra height of the pad. In this regard, the Court takes judicial notice of the fact that it is common, when storing an object in a container which is not tall enough to accommodate the excess height of the stored object without pressing against the top thereof. It would be obvious to increase the height of the cover for the gel cup in Baum et al patent No. 3,187,745 to accommodate the full height of the gel pad when not compressed, if desired.

64. The gel pad described and claimed in the '346 patent is not unique but is identical with that described in Baum et al patent No. 3,187,745. The only difference is in the cover for the pad which, in the Baum et al patent, compresses all of the Gel pad to the level of the rim o the cup while, in the '346 patent, the dimple in the cover compresses part of the gel pad

below the level of the rim of the cup and permits the remainder of the pad to remain above the level of the rim of the cup. Once the covers of the electrodes described in Baum patent No. 3,187,745 and the '346 patent are removed and the electrodes applied to a patient, the gel pads of both are compressed somewhat below the rim of the cup.

65. The specification of the '346 patent states in col. 3, lines 41-45 and col. 5, lines 59-63, that on applicaton of the electrode to the skin, the skin bulges into the cup member and that, therefore, the gel-soaked pad will be compressed when applied to the skin, even if it is no thicker than the depth of the cup member.

66. There is no functional or structural difference in the electrode claimed in claim 1 of the '346 patent and that described by Baum et al patent No. 3,187, 745 when the protective covers of each of

them are removed.

67. In view of the fact that in the NASA electrode the gel pad projects during storage and is compressed when applied to the astronaut's scalp, it would have been obvious to one skilled in the electrode art in May 1970, to have had the gel pad described in Baum et al patent No. 3,187,745.

68. Claim 8 of the '346 patent locates the gel pad and cover on an electrode such as shown in the '807 patent, which is prior art with respect to the Patrick et al patent, and does not describe an electrode any more novel than that described by claim 1, and is equally obvious to one of ordinary skill in the art.

69. The gel pad for the eletrolyte [sic] performs the same function in the electrode of the '346 patent as it did in similar structures of the prior art.

70. Plaintiff's contention that a pre-gelled electrode like that disclosed in the Patrick et al patent achieves a stabilization during storage at the interface between the electrolyte gel and the snap fastener so that when the electrode is applied to the patient no delay is necessary for stabilization is not to be ascertained from an examination of the patent itself. Stabilization would also have occurred in the prior art pre-gelled electrode including that shown in the original Szpur patent when made and used.

71. Neither Charles Patrick nor Roman Szpur, the inventors of plaintiff's pre-gelled disposable electrode, were aware at the time of their invention, or even later at the time of the filing of the patent application which issued as U.S. Patent No. 3,701,346, that the storage of the electrode with the gel pad in contact with the metal conduc tor would provide any

unexpected results. However, in late 1971, as the result of normal quality assurance testing procedures NDM learned that unexpected, substantial improvements in offset voltage were occurring after the electrodes had been gelled and stored.

G. THE LEVEL OF ORDINARY SKILL IN THE ART

72. The relevant time for determining the level of ordinary skill in the electrode design art in this case is the late 1969-mid 1970 time when the alleged inventions of plaintiff's patents here in suit were made. The prior patents, publications, and practices in the medical electrode art best indicate what the level of ordinary skill in the art was.

73. A person of ordinary skill in the electrode art at the end of 1969 had an engineering background, commonly in electrical engineering, was familiar with heart monitoring equipment and procedures,

understood the basic requirements of medical electrodes and was familiar with most of the medical grade materials and reusable and disposable electrodes on the market.

E. COMMERCIAL SUCCESS

74. In the early 1960's, there was almost no longterm cardiac monitoring of heart patients being carried out in hospitals. The need for a good medical electrode began to increase as the amount of monitoring of cardiac patients in hospitals began to increase during the mid-1960's, and the need for a good electrode had become greater by the late 1960's when nearly every hospital in the country was beginning to obtain monitoring equipment.

75. Plaintiff's electrodes which embody the inventions of the plaintiff's patents here in suit, have proved to be a very substantial commercial success. Defendants also have had commercial success

selling the accused electrodes.

76. When the plaintiff's pre-gelled disposable electrode was first offered in the fall of 1970, the electrode was approved and accepted in a very short time by many of the leading hospitals throughout the country, including Massachusetts General in Boston, the New England Medical Center in Boston, the Yale New Haven Medical Center, Johns Hopkins in Baltimore, the Mayo Clinic in Minnesota, and others.

77. The Hospital Supply Division of American Hospital Supply Corporation is the distributor of plaintiff's pre-gelled electrode, along with approximately 5,000 other items in its very broad product line. The plaintiff's pre-gelled electrode was the first product ever introduced by the Hospital Supply Division which experienced over a million dollars in sales within the first year of its introduction.

78. In the last quarter of 1970

during which the plaintiff's pre-gelled electrode was first introduced for sale, a quarter of a million electrodes were sold. In 1971, 4 million units were sold; in 1972, 12 million units were sold; in 1973 18 million units were sold; and, at the time of trial of this action, the electrodes were being sold at the rate of 30 million units per year. When plaintiff's predecessor Bionetics, Inc. first began to sell electrodes in the fall of 1970, only 10 to 15 people were employed. At present, plaintiff NDM Corporation employs over 650 people.

79. Plaintiff's prosecution of this infringement action was in good faith and was not frivolous and the Court has determined that it will not award attorneys fees in this action.

CONCLUSIONS OF LAW

1. Claims 15 and 17 of the original Szpur patent 3,696,807 and all of the

claims of Szpur patent Nos. 3,713,435 and 3,820,531 are invalid under Section 103, 35 U.S.C., as obvious in December 1969 to one of ordinary skill in the medical electrode art in view of the prior art.

2. Claims 1 and 8 of the Patrick et al patent 3,701,346 are invalid under Section 103, 35 U.S.C., as obvious in May 1970 to one of ordinary skill in the medical electrode art in view of the prior art.

3. Defendants are entitled to judgment dismissing the action of the plaintiff.

4. The Clerk shall enter judgment dismissing this action.

DATED at Seattle, Washington, this 21st day of October, 1977.

s/
United States District Judge

Approved as to form, but
not as to substance:

s/_____
Attorney for plaintiff

s/_____
Attorney for defendants

Opposition

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FILED
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CLERK

NO. 81-194

IN THE

Supreme Court of the United States

OCTOBER TERM 1981

NDM CORPORATION,
Petitioner,

v.

HAYES PRODUCTS, INC., and
JOSEPH H. JOHNSON,
Respondents.

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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I.

OPINIONS BELOW

The citation to the opinion in the United States Court of Appeals for the Ninth Circuit and copy of the opinion of the district court contained in the Petition for Writ of Certiorari are accurate.

II.

JURISDICTION

The statement of jurisdiction contained in the Petition is accurate.

III.

STATUTORY PROVISION INVOLVED

The Petition accurately and adequately sets forth the statutory provision involved.

IV.

STATEMENT OF THE CASE

A. The Patents in Suit

Although the validity of four NDM patents[1] for medical electrodes was challenged by Hayes in the district court

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[1] United States Patents No. 3,696,807 ("the '807 patent"); 3,701,346 ("the '346 patent"); 3,825,531; and 3,701,346; the latter two are continuation applications from the '807 patent.

action, NDM's Petition for Rehearing to the Court of Appeals for the Ninth Circuit was limited to the issue of the validity of claims 1 and 8 of the '346 patent[2]. NDM's petition is also so limited.

The three patents not at issue in this petition are also directed to medical electrodes for cardiac monitoring and are characterized by:

1. a rigid, nonconductive cup for holding an electrolyte gel;
2. a metal snap fastener mounted in the base of the cup to provide electrical conduction to a monitor lead from the patient via the electrolyte gel; and
3. an elastic sheet having an adhesive coating on one side covering

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[2]Pages 1-2, Appellant's Petition for Rehearing with Suggestion of Rehearing in Banc.

the cup, the elastic sheet, when pressed against the skin of a patient, holding the rim of the cup against the skin to prevent leaking of electrolyte gel from beneath the cup rim.

Though not claimed in the '807 patent, Figure 4 of that patent discloses a "pre-gelled" or "ready-to-use" electrode where the electrolyte gel is placed in the cup and covered with a protective cover.

The '346 patent, involved in this petition, discloses and claims an improvement over the '807 patent in the use of an absorbent pad placed in the cup and pre-filled with electrolyte gel, and a cover to protect the pad during storage. The '807 patent is prior art as respects the '346 patent.

B. Opinion of the District Court

In holding the '807 and '346 patents invalid under Section 103, 35 U.S.C., the

district court made extensive findings and properly applied the three-pronged Section 103 test[3] outlined by this court in Graham v. John Deere, 383 U.S. 1, 17 (1966). The findings[4] of the district court reflect its adherence to Graham, supra.

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[3] In its oral decision, the trial court stated:

> I have sought to apply the criteria for obviousness laid down in the Supreme Court in Graham v. John Deere Co., [383 U.S. 1 (1966)] and, therefore, have considered: (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art -- and that I find that with respect to all the claims at issue, the differences between the subject matters sought to be patented and the prior art are such that the subject matters as a whole would have been obvious at the time the inventions were made to persons having ordinary skill [and] in the art of medical electrode design.

[4] Findings 31 to 44 -- Scope and Content of the Prior Art -- reproduced on pp. B-17 to B-34 of the petition;

Finding No. 71,[5] included as one of the findings assessing the differences between the prior art and the claims of the '346 patent, reflects the finding of the trial court based on the testimony of Charles Patrick -- and the testing of an NDM electrode in 1971 having a silver snap

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(Footnote 4 continued)

Findings 59 to 71 -- The Difference Between the Prior Art and the Claims of the '346 patent -- reproduced on pp. B-40 to B-47 of the petitions;

Findings 72 and 73 -- The Level of Ordinary Skill in the Art -- reproduced on pp. B-46 and B-47 of the petition.

[5] 71. Neither Charles Patrick nor Roman Szpur, the inventors of plaintiff's pregelled disposable electrode, were aware at the time of their invention, or even later at the time of the filing of the patent application which issued as U.S. Patent No. 3,701,346, that the storage of the electrode with the gel pad in contact with the metal conductor would provide any unexpected results. However, in late 1971, as the result of normal quality assurance testing procedures NDM learned that unexpected, substantial improvements in offset voltage were occurring after the elctrodes had been gelled and stored.

fastener and a chloride-containing electrolyte gel. It is significant to note that the "unexpected results" referred to in Finding No. 71 has reference, not to "a person of ordinary skill in the art" who, under Section 103, is charged with knowledge of all relevant prior art disclosed at the time of his invention,[6] but only to the testimony of Charles Patrick that neither he nor Roman Szpur, the co-inventor of the '346 patent, were aware at the time of the making of the electrode described in the '346 patent, that improvements in offset voltage would occur after the pre-gelled electrode was stored.

As in its appeal to the court of appeals, NDM in its present petition

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[6] Graham v. John Deere, supra, at 6; Walker v. General Motors Corp., 362 F.2d 56, 60 (9th Cir. 1956).

attempts to have the trial court's Finding No. 71 interpreted to support its claim of "synergism" or "unexpected results" as being unexpected to the hypothetical person of ordinary skill in the art under Section 103. Such an expanded interpretation is not supported by the trial record nor was it the meaning intended by the trial court.

C. Opinion of the Court of Appeals

In its opinion[7] the court of appeals discussed NDM's efforts in developing the medical electrodes disclosed in the '807 and '346 patents, indicated that the statutory presumption of validity was overcome by pertinent prior art[8] not before the patent examiner, applied the three-part

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[7] 641 F.2d 1274 (also reproduced as pp. A-1 to A-29 of the petition).

[8] The publication numbers 6-10 in n. 4 of the decision of the Court of Appeals.

factual test set forth in Graham, supra, took into account commercial success as a secondary consideration of nonobviousness, and concluded that the district court had substantial evidence to find the claimed subject matter of the '807 and '346 patents obvious. Then the Court commented on synergism, although not necessary for its affirmance of the district court decision. As a final statement in its opinion, the Court said that its conclusion that the district court had substantial evidence to find the NDM patents invalid for obviousness "subsumes within it a finding that the patents lack synergism".

The court of appeals' decision did not ride in any way on the questions of whether or not there is a test for synergism more strict than the usual rule of Section 103; i.e., if there is not such a stricter test, the district court's decision would still have been affirmed. Nevertheless, it is

the court of appeals' discussion respecting synergism on which NDM has based its petition.

V.

ARGUMENT

A. The Court of Appeals Did Not Rely on a Separate "Synergistic" Test Applied Only to Combination Patents In Affirming the Invalidity of the Claims of the '346 Patent

Contrary to NDM's implication in the first of its "Questions Presented" by the petition, the court of appeals did not rely on a separate "synergistic" test in affirming the holding of the district court that the claims of the '346 patent were invalid for obviousness. The court of appeals in its Opinion, attached as Appendix A to the petition at pp. A-22 to A-25, stated:

> The patentable differences between the '807 and '346 patents were the present configuration of the gel-soaked pad and its cup member and the presence and configuration of the cover for the gel-soaked pad. . . .

Essentially, the only difference between the '346 patent and the Baum '745 patent is in the protective cover for the pad. The Baum '745 compresses all of the gel to the level of the rim of the cup. In the '346 patent, on the other hand, the dimple and the cover compresses part of the gel below the level of the rim of the cup, permitting the rest of the gelled pad to remain above that level.

The District Court believed this difference to be obvious. Substantial evidence supports the findings. . . .

Even without this disclosure, the Court could have found the '346 patent obvious. There is no functional difference between the Baum '745 and the '346, once the protective cover of each is removed. It may well be, as NDM argues, that the '346 was an improvement over the '745, achieving a more stable gel column when applied to the skin. But "in applying Section 103 . . . the test is not whether the object is an improvement in the art; . . ." but whether an improvement is obvious to one skilled in the art. Reinke Mfg. Co., Inc. v. Sidney Mfg. Corp. 594 F.2d 644, 646 (8th Cir. 1979). "[A]n improvement which is obvious . . . is not entitled to protection." Id. The record supports the trial court's conclusion that the '346 patent was obvious to one skilled in the art.

It was only after reaching this conclusion that the Court then referred to synergism and to Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.[9] The matter of synergism and a combination of old elements was not new to this Court in 1950 when considered in the A & P case under the label "aggregation." At least as early as 1885 the Supreme Court had considered "aggregation," in the same light in John Stephenson v. Brooklyn Cross-Town R.R., 114 U.S. 149 (1885):

> Neither one of the three elements of the alleged combination performs any new office or imparts any new power to the others, and, combined, they do not produce any new result or any old result more cheaply or otherwise more advantageously. There is, therefore, no patentable combination.

As indicated in Anderson's Black Rock v. Pavement Salvage Co., 396 U.S. 57, 61 (1969), a synergistic result is achieved

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[9] 340 U.S. 147 (1959), reh. denied, 340 U.S. 918 (1951).

when a combination of old elements results in an effect greater than the sum of the several effects taken separately. This definition was repeated in Sakraida v. Ag Pro. Inc., 425 U.S. 273, 282 (1976), wherein, at 281, the Court followed its admonition in the A & P case, that "Courts should scrutinize combination patent claims with a care proportioned to the difficulty and improbability of finding invention in an assembly of old elements". Since, as commented in Reeves Instrument Corp. v. Beckman Instruments, Inc., 444 F.2d 263, 270 (9th Cir. 1971), "all mechanical and electrical devices [are] constructed of old elements", and "all chemical products are the result of combining known chemical elements", synergism, if it be a requirement for patentability where only old elements are included, appears to apply to substantially all inventions when

considering non-obviousness under Section 103. Certainly it inherently applied to the inventions considered in Graham, supra, when the three-pronged test for obviousness was enunciated. The court of appeals did not depart from this three-pronged test when affirming that the NDM patents were invalid, nor did they disregard any of the findings when making this test.

B. Finding 71 of the District Court Was Considered by the Court of Appeals In Its Affirmation of the District Court's Holding of Invalidity of the Claims of the '346 Patent

Finding 71 concerns the fact that an improvement in offset voltage occurs when a pre-gelled electrode having a gel pad is stored for an unspecified period of time before being used on a patient. The finding states that this improvement was unexpected and was not known to the joint inventors of the '346 patent when it was

filed but was learned by NDM in late 1971 as a result of normal quality assurance testing procedures. On p. 11 of its petition NDM states the improvement was unexpected by the inventors and that they were men skilled in the relevant art. However, this is not stated in Finding 71, and the record only supports NDM's statement to the extent that joint inventor Patrick did not expect the improvement in offset voltage from storage. In other words, Finding 71 does not state that this improvement would have been unexpected to a person of ordinary skill (under Section 103) in the medical electrode art when the invention was made had that hypothetical person been familiar with all of the pertinent prior art. Joint inventors Patrick and Szpur clearly were not familiar with all of the pertinent prior art.

The improvement in offset voltage referred to in Finding 71 is due to stabilization of the interface between a chloride-containing electrolyte gel and the silver snap fastener serving as the electrical contact. This stabilization is discussed in Finding 70,[10] which concludes by stating that the stabilization "would also have occurred in the prior art pre-gelled electrode[s] including that shown in the original Szpur patent [the '807 patent] when made and used".

Finding 71 must also be considered in conjunction with Finding 69,[11] which states that the gel pad "performs the same function in the electrode of the '346 patent as it did in similar structures of the prior art". This Finding alone shows that the '346 electrode lacked synergism.

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[10] P. B-45 of the petition.

[11] P. B-44 of the petition.

Hence, it is seen that when all of the findings of the district court are considered, there is not any need for a special strict test involving synergism to justify a finding of obviousness. Clearly, the district court and the court of appeals were correct in holding the patents invalid under Section 103 in view of the prior art without relying on any special or stricter test.

Nevertheless, the second of the "Questions Presented" in the petition infers that the court of appeals failed to consider Finding No. 71 of the opinion of the district court in its application of Section 103 in affirming the trial court's holding of invalidity of the claims of the '346 patent. Clearly, that is not so. The court of appeals stated in its opinion reproduced on p. A-24 of the petition: "It may well be as NDM argues that the '346 was

an improvement[19] over the '745, achieving a more stable gel column when applied to the skin".

Footnote 19 states: "The Trial Court found the improvement to be substantial." The court of appeals could only have been referring to Finding 71 of the district court, as it is the only finding which makes reference to a "substantial" improvement.

C. This Case Should Not Be a Vehicle For Resolving a Conflict Between Circuits

The Court of Appeals for the Ninth Circuit only used the synergism test discussion at the end of its opinion to indicate that, inherent in the district court's decision was a finding that the invention of the '346 patent lacked synergism. This manner of showing lack of synergism was unnecessary, particularly in view of Finding 69 as indicated above.

Respondents do not dispute that at times there appears to be conflict among the courts of appeal for the various circuits respecting the proper use of synergism as a test of patentability. However, as has been indicated in this argument, the outcome of this case did not depend upon any synergism test for patentability. If the conflict is ripe for review, such should not be considered entirely in the abstract, but should be reviewed in a case where the result of the reviewed case hinges on the resolution of the conflict. Respondents should not be put to the monetary expense of such a review.

VI.

CONCLUSION

The district court and the court of appeals correctly held the claims of the '346 patent invalid by proper application of the Section 103 test as laid down by this Court in Graham, supra.

The court of appeals did not rely on synergism as a separate test of patentability in addition to Section 103.

The court of appeals correctly considered Finding 71, referring to unexpected results, in its application of Section 103, and not by way of an application of a separate synergism test for patentability. If there is a conflict between the Ninth Circuit and the Seventh and Tenth Circuits respecting synergism as a separate test of patentability, the conflict did not effect the outcome of this case in the Ninth Circuit.

The petition should be denied.

DATED at Seattle, Washington, this 19th day of November, 1981.

Respectfully submitted,

SEED, BERRY, VERNON & BAYAHAM

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Petitioner's Reply Brief

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NO. 81-194

IN THE

Supreme Court of the United States

OCTOBER TERM 1981

NDM CORPORATION,
Petitioner,

v.

HAYES PRODUCTS, INC., and
JOSEPH H. JOHNSON,
Respondents.

REPLY BRIEF OF PETITTIONER

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PETITIONER'S REPLY BRIEF

The respondent's brief in opposition to the Petition for Writ of Certiorari raises the issue that this case is not a proper vehicle for resolving a conflict between the circuits because the court of appeals did not rely on a separate "synergistic" test to hold U. S. Patent No. 3,701,346 invalid.

This argument is without merit.

Respondent acknowledges that the Ninth Circuit postulates and applies a separate "synergistic" test of patentability for combination devices. In its opinion, the Ninth Circuit also specifically noted that, contrary to its view, the Seventh and Tenth Circuits recently had rejected synergism as a separate test of patentability because of its inconsistency with Section 103 analysis.[1]

Respondent's argument fails to grasp that the Ninth Circuit Court of Appeals, by erroneously emphasizing synergism as a separate test of patentability, misapplied the true test of patent validity under 35 U.S.C. Section 103 by failing to consider in applying this test that the invention of the '346 patent produced " . . . surprising

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[1] A-27.

and unexpected improvements in offset voltage".[2] The trial court also found, as acknowledged by the court of appeals, that the improvements in offset voltage were "substantial" (A-24, n.19; B-45, B-46; F.F. 71).

The key language which elucidates the error of the court of appeals, and which has been quoted by both petitioner and respondent, is as follows:

> It may well be as NDM argues that the '346 was an improvement over the '745, achieving a more stable gel column when applied to the skin. But "[i]n applying Section 103 . . . the test is not whether the object is an improvement in the art; . . ." but whether an improvement is obvious to one skilled in the art.[3]

In light of the trial court's finding that the invention of the '346 patent produced " . . . unexpected, and substantial

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[2] A-29, n.20.

[3] A-24, A-25.

improvements"[4], the court of appeals should have found that the '346 patent met this test of patentability and that the patent was valid. The court failed to reach this seemingly apparent conclusion because of its erroneous view that a finding of " . . . unexpected, and substantial improvements" relates only to the separate test of synergism and should not be considered in connection with the application of the obviousness test of Graham v. John Deere Co.[5]

CONCLUSION

The present case presents a perfect vehicle for resolving the conflict between

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[4] B-45, B-46; F.F. 71.

[5] 383 U.S. 1, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966).

the circuits[6] as to the proper test of validity under 35 U.S.C. Section 103, and specifically whether a patent for a combination of old elements must meet a separate "synergistic" requirement.

Respectfully submitted,

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[6]Besides the rejection of synergism as a separate test of patentability by the Seventh and Tenth Circuits, which was acknowledged by the court of appeals in its opinion, the Third Circuit in the case of Molins Machine Company v. Rengo Co., (3d Circuit, July 20, 1981) has now also rejected synergism as a separate test of patent validity.